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BARIUM STEARATE
(CAS NO. 6865-35-6):
TEST PLAN

Submitted to the US Environmental Protection Agency

By

Chemtura Corporation

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SUMMARY

Chemtura Corporation (Chemtura) has sponsored Barium stearate (CAS No. 6865-35-6) under the EPA's High Production Volume (HPV) Program. This document provides the Test Plan and summaries of existing data for this substance.

1.0 INTRODUCTION

Chemtura has voluntarily committed to participate in the Environmental Protection Agency's (EPA) high production volume chemicals (HPV) challenge program, to assess the health and environmental hazards, including selected physical chemical characteristics of barium stearate (CAS No. 6865-35-6).

An evaluation of the available data and proposed test plan are included in this document. As part of this evaluation, data from dissociation products was used to fulfill some endpoints for the sponsored substance. Robust summaries for barium stearate and dissociation products are provided in Appendix 1.

The objective of this test plan is to evaluate the available data and determine what additional data, if any, are needed to adequately characterize the physical properties, environmental fate, and human health and environmental effects of barium stearate. It is proposed that additional studies be conducted as shown in Table 1.

Table 1: AVAILABLE DATA FOR BARIUM STEARATE

Endpoint	
Physical Chemical Properties	
Melting Point	A
Vapor Pressure	Estimated/Not relevant*
Boiling Point	Estimated/Not relevant*
Partition Coefficient	Estimated/Not relevant** R (B,S)
Water Solubility	A
Environmental Fate	
Hydrolysis	Not relevant**
Photodegradation	A
Biodegradation	R (S)
Environmental Transport	A
Ecotoxicity	
Acute Fish	Not relevant*** R (B)
Acute Daphnia	Not relevant*** R (B,S)
Acute Algae	Not relevant*** R (B)
Chronic Daphnia	Test
Mammalian toxicity	
Acute Oral	A
Repeated Dose	R (B,S)
Genotoxicity (*in vitro* -bacteria)	R (B,S)
Genotoxicity (*in vivo*)	R (B,S)
Reproductive/Developmental	R (B)

A= Adequate data
Not relevant*= due to the solid nature of the substance
Not relevant**= the substance readily dissociates
Not relevant***= Based on the low water solubility of barium stearate, the estimated high partition coefficient for barium stearate and the high partition coefficient of stearic acid, a chronic daphnia test is proposed
R = Read across to dissociation products: B= barium/compounds, S= Stearic acid
Test = Testing is proposed
Estimated = Value calculated using EPIWIN

2.0 POTENTIAL USE AND EXPOSURE

Barium stearate is a solid material used as a lubricant/processing aid in PVC compounding.

3.0 EVALUATION OF EXISTING DATA AND PROPOSED TESTING

One key characteristic of barium stearate is that it readily dissociates from an ion pair into free metal and free acid. Barium stearate is found as a partially dissociated product in the ambient environment (i.e., neutral pH). Dissociation is a reversible process and the portion of dissociated salt present is dependent on the pH and pKa (the dissociation constant), which is the pH at which 50% dissociation occurs. In the low pH environment of the digestive tract (e.g., pH 1.2) complete dissociation will occur. The transport and bioavailability of the metals and acids are determined by their solubility in environmental media and biological fluids which is determined by environmental parameters such as pH.

Dissociation studies have been conducted for barium stearate and the results show that significant dissociation will occur at approximately neutral pH (i.e., representative of aquatic and marine ecosystems), while complete dissociation will occur at physiologically relevant pH of the mammalian stomach (pH 1.2) (Lezotte, F.J. and W.B. Nixon, 2002). These findings are particularly important in relating available data for the respective acids and metals to support the existing data and in the fulfillment of critical endpoints.

The dissociation constant is important for two reasons. First, it determines the proportion of any specific acid or metal that is dissociated at a given pH. The free acid and corresponding free metal are often much different than the salt (ion pair) moiety in characteristics such as solubility, adsorption, and toxicity. The proportion of dissociation influences the behavior of the substance in the environment and the bioavailablity of the acid and metal constituents of metal carboxylate salts.

The dissociation constant indicates that barium stearate has a pKa (pKb) values (pKa1) in the neutral range (6.706). This indicates that in the neutral pH range, significant portions of the metal carboxylate will be dissociated. In addition, at the low pH of the mammalian stomach (pH 1.2) all of the metal carboxylate would be expected to be completely or nearly completely dissociated. This indicates that the absorption and any observed toxicity would be independent for the respective acid and metal when administered orally.

The dissociation constants show that at the pH of the stomach and at the pH of environmental media the important moieties are the ionized free acid and metal. Because of this, data for environmental fate, ecotoxicity, and mammalian toxicity of the free acid, or that for a simple salt (e.g., the sodium salt), can serve as surrogate data for the acid component of respective metal carboxylates. Similarly, under these conditions, data for the metal ion can be represented by fate and toxicity data of free metal ion or simple metal salts (e.g., barium chloride). Therefore, the role in any observed toxicity for acids and metals can be evaluated independently (i.e., as the free metal and/or free acid).

In this test plan, the dissociation products [represented by barium (CAS No. 7440-39-3), barium chloride (CAS No. 10361-37-2) and barium sulfate (CAS No. 7727-43-7), as well as stearic acid (CAS No. 57-11-4)] are used to supplement the physical/chemical properties, environmental fate, aquatic toxicity and mammalian toxicity endpoints for barium stearate.

The available data have been assessed (see Tables 2 through 5). Robust summaries are provided as Appendix 1.

Chemical/Physical Properties:

Barium stearate is a solid. The determination of physical and chemical properties is limited by physical state (solid) and low water solubility. Physical chemical properties are provided in Table 2. The melting point of barium stearate is 160 °C (NISC BiblioLine, 2005). A boiling point has not been determined; the estimated boiling point is 661 °C (EPI SUMMARY, 2005). A vapor pressure has not been determined but it is expected to be negligible, and is not appropriate for determination. The modeled vapor pressure is $7.52E^{-14}$ mm Hg (0 hPa) (EPI SUMMARY, 2005). The physical and chemical properties of the dissociation products of barium stearate are also provided in Table 2. With the exception of barium chloride, the dissociation products of barium stearate have very low water solubility's.

Table 2: Summary of Physical and Chemical Property Data for Barium Stearate and Dissociation Products

Compound	Physical Chemical Properties			
	Melting Point (°C)	Boiling Point (°C)	Vapor Pressure (hPa)	Water Solubility
Barium stearate	160	* 661 Not relevant	* 0 Not relevant/ Negligible	3.5 mg/L at 20 °C
Dissociation products				
Barium	~710[2]	~1600[2]	*** Not relevant/ Negligible	*** Not relevant/ Negligible
Barium sulfate	1580[1] (decomposes)	1149[1]	*** Not relevant/ Negligible	Insoluble**[2]
Barium chloride	963[2]	1560[3]	*** Not relevant/ Negligible[3]	37.5 g/100 cm3 at 26 °C[4]
Stearic acid	69-70[5]	383[5]	1.33 at 174°C[6]	.568 mg/l at 25 °C[7]

* = Barium stearate is a solid; determination of boiling point and vapor pressure is not appropriate
** = 1 gram in 400,000 parts
*** = not relevant for metals/metal compounds

Recommendation: No additional testing proposed.

Environmental Fate:

The determination of partition coefficient, hydrolysis and biodegradation are not relevant for barium stearate due to its low water solubility and ready dissociation. As discussed above, barium stearate readily dissociates rather than hydrolyzing in water. Photodegradation and fugacity modeling has been conducted for barium stearate (EPI SUMMARY, 2005). The photodegradation half-life is 0.249 days. Level III fugacity modeling indicates barium stearate will partition primarily to soil and sediment.

Modeled partition coefficients for barium compounds are low (Table 3) (EPI SUMMARY, 2005). Hydrolysis of barium compounds is not relevant as they will dissociate and ionize in water. Photodegradation modeling cannot be conducted for these substances (EpiWin results are presented in Appendix 2). Level III fugacity modeling indicates distribution to soil and water for barium chloride and barium sulfate. Barium is expected to distribute primarily to air and water. For barium compounds, biodegradation is not expected to occur.

Stearic acid has a high partition coefficient (Leo, A.J., 1978) and low water solubility (Robb, ID, 1966) and is hydrolytically stable. Photodegradation modeling indicates a half-life of 0.5 days (EPI

1 ATSDR (1992)
2 O'Neil, MJ, Smith, A, Heckelman, PE and JR Obenchain (eds.) (2002)
3 Department of Health and Human Services, National Institute of Occupational Safety and Health (1990)
4 Http:/en.wikipedia.org/wiki/Barium Chloride (2005)
5 Windholz, M. (1982)
6 Weast, R.C. (1969)
7 Robb ID (1966)

SUMMARY, 2005). Fugacity modeling indicates distribution primarily to soil and sediment (EPI SUMMARY, 2005). Stearic acid is readily biodegradable (King, E.F.and Painter, H.A., 1983; Novak, J.T. and Kraus, D.L., 1973; Ruffo, C., Galli, E., Arpino, A., 1984; Urano, K. and Saito, M., 1985).

Table 3 Summary of Environmental Fate Data for Barium Stearate and Dissociation Products

Compound	Environmental Fate				
	Partition Coefficient	Stability in Water	Photodegradation	Level III Fugacity Model	Biodegradation
Barium stearate	** 15.4	**/****	$T_{1/2}$ = .249 days Overall OH Rate Constant = 42.9098 E-12 cm3/molecule-sec	Air 0.0807 Water 2.32 Soil 30.7 Sediment 66.9	***
Dissociation products					
Barium	** 0.23 (Epiwin)	**/****	**** Not relevant	Air 37.9 Water 55.8 Soil 6.18 Sediment 0.0944	***
Barium sulfate	** 0.63 (Epiwin)	**/****	**** Not relevant	Air 1.42e-006 Water 47.4 Soil 52.5 Sediment 0.091	***
Barium chloride	** 0.85 (Epiwin)	**/****	**** Not relevant	Air 9.42e-006 Water 46 Soil 53.9 Sediment 0.0906	***
Stearic acid	8.42	Stable	T ½ = .5 days Overall OH Rate Constant = 22.4804 E-12 cm3/molecule-sec	Air: 0.676 Water: 7.19 Soil: 28.9 Sediment: 63.3	= 77 % after 28 day(s)

** = Not relevant; substance readily dissociates
*** = Barium compounds are not expected to be readily biodegradable
**** = Can not be modeled with EPIWIN

Recommendation: No additional testing proposed.

Aquatic Toxicity

Aquatic toxicity data are not available for barium stearate. Data are available for barium and stearic acid, with 96 hr LC50 values in fish of >500 (Heitmuller, P.T., T.A. Hollister and P. R. Parrish, 1981) and 12 mg/l (Leach, J.M. and A.N. Thakore, 1977), respectively. The LC50 value (exposure period not specified) for barium chloride in fish is 42.7 mg/l (US EPA AQUIRE database, 2005). 48 hr LC50 values for daphnia are 68 mg/l (barium; LeBlanc, G.A.), 2.81 – 32 mg/l (barium sulfate; US EPA AQUIRE database, 2005; Khangarot BS and PK Ray, 1989) and 14.5 mg/l (barium chloride; Biesinger, KE and GN Christensen, 1972). The 96 hr EC50 value for algae is 25 mg/l (barium chloride; Wang, W, 1986). Aquatic toxicity data for daphnia and algae are not available for stearic acid.

Recommendation: Based on the low water solubility of barium stearate, the high predicted partition coefficient for barium stearate and the high partition coefficient of stearic acid, a chronic daphnia test is proposed.

Table 4 Aquatic Toxicity Data for Barium Stearate and Dissociation Products

Compound	**Environmental Effects**		
	96 hr LC50 Fish (mg/L)	48 hr LC50 Daphnia (mg/L)	96 hr EC50 Algae (mg/L)
Barium stearate	Not relevant*	Not relevant*	Not relevant*
Dissociation Products			
Barium	>500	410	Not available
Barium sulfate	LC0 = 59000	32 2.81	Not available
Barium chloride	42.7**	14.5	25
Stearic acid	12	Not available	Not available

Not relevant*= Based on the low water solubility of barium stearate, ready dissociation, and high partition coefficient of stearic acid, acute aquatic toxicity testing is not appropriate.
**Exposure period not specified

Acute Mammalian Toxicity:

Barium stearate has a low acute oral toxicity, with LD50's ranging from 2506 (Gigiena Truda i Professional'nye Zabolevaniya) to 3390 (Crompton Corporation, 2004) mg/kg (rat) and 1832 mg/kg (mouse) (Gigiena Truda i Professional'nye Zabolevaniya) (Table 5). Barium chloride has a much higher acute toxicity, most likely due to the higher water solubility, with values of 132 to >2000 (barium chloride dihydrate) mg/kg in rats (Tardiff, RG, M Robinson, NS Ulmer, 1980; National Toxicology Program, 1994) and >692 ppm (barium chloride dihydrate) in mice (National Toxicology Program, 1994). Stearic acid has a low acute oral toxicity, with an LD50 value of 4600 mg/kg (rat; Clayton, G.D., F.E. Clayton, 1993-1994).

Recommendation: No additional testing is proposed.

Repeated Dose Toxicity:

Repeated dose toxicity studies have not been conducted with barium stearate. However, both barium chloride and stearic acid have been tested. In a 13 week study of barium chloride dihydrate, rats received 125, 500, 1000, 2000 or 4000 ppm barium chloride in drinking water (National Toxicology Program, 1994). Three high dose males and one high dose female died during the last week of the study. Final mean body weights of the high dose group animals were significantly lower than controls. Water consumption at 4000 ppm was 30% lower than controls. There were no substance-related neurobehavioral, cardiovascular or clinical signs. Serum phosphorous levels were significantly higher than controls in both sexes in the 2000 and 4000 ppm groups. Renal tubule dilatation was observed in both sexes of the high dose group. The NOAEL was 1000 ppm. A 13 week study was also conducted in mice under the same protocol as described for rats above (National Toxicology Program, 1994). Six high dose males and seven high dose females died. One male in the 125 ppm group also died. Final mean body weights of the high dose group animals were significantly lower than controls. Water consumption was 18% lower than controls. Debilitation was observed in high dose animals. Absolute and/or relative liver weights were significantly lower in the 1000, 2000 and 4000 ppm group animals. Multifocal to diffuse nephropathy was observed in the high dose group. The NOAEL was 500 ppm. In a 13 week drinking water study, rats were exposed to 10, 50 or 250 ppm barium chloride dihydrate (Tardiff, RG, M Robinson, NS Ulmer, 1980). Animals were sacrificed at 4, 8 and 13 weeks. No effects were observed for food consumption, clinical signs, body weight, hematology, serum enzymes, serum ions, gross pathology and histopathology. Water consumption was slightly decreased in the high dose animals. A slight decrease in relative adrenal weight was observed in treated animals versus controls. Increased dose resulted in increased concentrations in barium in liver, skeletal muscle, heart and bone. In a 14 day drinking water study, rats were exposed to 125, 250, 500, 1000 or 2000 ppm barium chloride (National Toxicology Program, 1994). There were no findings other than reduced water consumption at the high dose. The NOAEL was 1000 ppm. In a 14 day drinking water study, mice were exposed to 40, 80, 173, 346, 692 ppm barium chloride (National Toxicology Program, 1994). Increased relative and absolute liver weights were observed in high dose group animals. The NOAEL was 346 ppm.

Rats fed 50 g/kg/day stearic acid for 24 weeks developed reversible lipogranulomas in adipose tissue (Clayton, G.D., F.E. Clayton, 1993-1994). No significant pathological lesions were observed in rats fed 3000 ppm stearic acid orally for about 30 weeks, but anorexia, increased mortality, and a greater incidence of pulmonary infection were observed. Stearic acid is one of the least effective fatty acids in producing hyperlipemia, but the most potent in diminishing blood clotting time. Rats fed 6% stearic acid for 9 weeks showed a decreased blood clotting time and hyperlipemia (Clayton, G.D., F.E. Clayton, 1993-1994). When diets containing 5 to 50% stearic acid (as the monoglyceride) were fed to weanling mice for 3 weeks, depression of weight gain was seen above the 10% dietary level (Clayton, G.D., F.E. Clayton, 1993-1994). Mortality occurred only with the 50% diet. The effects were less noticeable in adult mice.

Recommendation: No additional testing is proposed.

Reproductive/Developmental Toxicity:

Reproductive toxicity studies have not been conducted with barium stearate. A reproductive study has been conducted with barium chloride. Rats were exposed for 60 days prior to mating to 1000, 2000 or 4000 ppm barium chloride dihydrate in drinking water (WHO Environmental Health Criteria, 1990). There were no signs of reproductive or developmental toxicity. The NOAEL for reproductive or developmental toxicity was 4000 ppm. Mice were exposed for 60 days prior to mating to 500, 1000, or 2000 ppm barium chloride dihydrate in drinking water (WHO Environmental Health Criteria, 1990). There were no signs of reproductive or developmental toxicity. The NOAEL for reproductive or developmental toxicity was 2000 ppm.

There are no reproductive or developmental studies with stearic acid. However, stearic acid is the most common of the long-chain fatty acids. It is found in many foods, such as beef fat, and cocoa butter. It is widely used as a lubricant, in soaps, cosmetics, food packaging, deodorant sticks, toothpastes, and as a softener in rubber. Long-term safe use of this substance precludes the necessity for additional testing.

Recommendation: No additional testing is proposed.

Mutagenicity Assays:

No genetic toxicity testing is available for barium stearate. Barium chloride is negative for bacterial and mammalian genotoxicity (National Toxicology Program, 1994; Rossman, TG, M Molina, L Meyer, P Boone, CB Klein, Z Wang, F Li, WC Lin, and PL Kinney, 1991; National Toxicology Program, 1983). There are no mutagenicity assays with stearic acid. However, stearic acid is the most common of the long-chain fatty acids. It is found in many foods, such as beef fat, and cocoa butter. It is widely used as a lubricant, in soaps, cosmetics, food packaging, deodorant sticks, toothpastes, and as a softener in rubber. Long-term safe use of this substance precludes the necessity for additional testing.

Recommendation: No additional testing is proposed.

Table 5 Mammalian Toxicity Data for Barium Stearate and Dissociation Products

Compound	Mammalian Toxicity				
	Oral LD50; (mg/kg)	Repeat Dose Toxicity	Repro. Effects	Develop. Effects	Genetic Toxicity
Barium stearate	3390 (rat) 2506 (rat) 1832 (mouse)	Not available	Not available	Not available	Not available
Dissociation Products					
Barium	Not available	Not available	Not available	Not available	Not available
Barium sulfate	Not available	Not available	Not available	Not available	Not available
Barium chloride	132 (rat) >2000 (rat) >692 ppm (mouse)	NOAEL = 1000 ppm (13 week, rat, drinking water) NOAEL = 500 ppm (13 week, mouse, drinking water) NOAEL = 1000 ppm (14 d, rat, drinking water) NOAEL = 346 ppm (14 d, mouse, drinking water) NOAEL = 50 ppm (13 week, rat. Drinking water) NOAEL = 209 (10 d, rat, drinking water) LOAEL = 100 mg/l (16 month, rat, drinking water)	NOAEL = 4000 mg/l (rat, drinking water) NOAEL = 2000 mg/l (mouse, drinking water)	NOAEL = 4000 mg/l (rat, drinking water)	Negative (bacterial mutation; in vitro chromosome aberration)
Stearic acid	4600 (rat)	50 g/kg/d for 24 weeks produced reversible lipogranulomas in rats. 6% for 9 weeks produced decreased blood clotting time and hyperlipemia in rats. NOAEL = 5% for 3 weeks (mice)	Not available	Not available	Not available

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